UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,642	10/11/2001	Jonathan M. Cohen	112163.124 U	1956

7590 05/19/2004

Hale & Dorr
1455 Pennsylvania Avenue N W
Washington, DC 20004-1008

EXAMINER	
YANG, NELSON C	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,642	COHEN, JONATHAN M.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-8,11,12 and 14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-8,11,12 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 3, 5-8, 11, 12, 14-20 and of the specification is acknowledged and has been entered.

2. Applicant's addition of claims 21-23 is acknowledged and has been entered.

3. Applicant's cancellation of claims 1-2, 4, 9-10, 13 is acknowledged.

4. Claims 3, 5-8, 11, 12, 14-23 are currently pending.

Rejections Withdrawn

5. Applicant's arguments, see p.8-9, filed March 22, 2004, with respect to the objections over the specification and claims 8 and 11 have been fully considered and are persuasive. The objections of the specification and claims 8, 11 has been withdrawn.

6. Applicant's arguments, see p.9-10, filed March 2, 2004, with respect to the rejections of claims 3, 5-8, 11, 12, 14-20 over 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 3, 5-8, 11, 12, 14-20 under 35 U.S.C. 112, second paragraph, has been withdrawn.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3, 5-8, 11, 12, 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kononen et al [Kononen et al, Tissue microarrays for high-throughput molecular profiling of tumor specimens, Nature Med. July 1998, 4(7), 844-847] in view of Kalra [US 5,948,359].

With respect to claims 3, 5-7, 20-23, Kononen et al teach providing a plurality of tissue microarrays (p.844, cols. 1-2), providing DNA, RNA or protein targets in each of the tissue samples in the arrays (p.844, col.1), providing and applying stains to that bind to the target molecule in situ to the tissue microarrays (p.847, col.1), and correlating extent of stain binding with clinical utility of the target molecule, such as markers for determining the presence of tumours (p.847, col.1), in order to establish the diagnostic, prognostic and therapeutic importance of emerging cancer gene candidates (abstract). Although Kononen et al teach the use of automation to permit simultaneous construction of multiple tumor array blocks, Kononen et al do not specifically disclose that the staining is automated in a high throughput manner.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to automate the staining, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192. Furthermore, Kalra et al teach that modern laboratories find it desirable to automate the staining process in order to examine large numbers of tissue specimens (column 1, lines 16-31). Therefore it would be obvious to use an automated stainer to stain the tissue samples in a high-throughput manner in the method disclosed by Kononen et al, in order to examine large numbers of tissue specimens.

9. With respect to claims 8, 11, 12, Kononen et al teach that the use of DNA, RNA, or protein targets in each of hundreds of tissue specimens in an array (p.844, col.1).

10. With respect to claim 17-19, Kononen et al teach a tissue microarray that has a solid surface with tissue samples mounted to the solid surface (p.844, column 1). Kononen et al do not teach the use of a bar code labeled slide for identifying how the tissues are to be treated by a machine.

Kalra et al, however, does teach the use of slides with bar code labels for optional features that can be included on the apparatus include devices intended to ensure level operation, to protect against electric shock, to verify that an appropriate tip has been selected and properly placed on the tip head, or to optically scan slides in a microscope slide tray or other container for microscope slides so that a user is not required to enter information into the computer (column 20, lines 1-15). Therefore, it would be obvious to use slides with bar-code labels in the method of Kononen et al, as suggested by Kalra et al, so that a user is not required to enter information into the computer.

11. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kononen et al [Kononen et al, Tissue microarrays for high-throughput molecular profiling of tumor specimens, Nature Med. July 1998, 4(7), 844-847], in view of Kalra et al [US 5,948,359] as applied to claims 1-13, 17-20 above, and further in view of Bogen et al [US 6,183,693].

Kalra et al teach the use of an automated stainer capable of heating (column 6, lines 4-19), but do not teach that the automated stainer comprises a first heater and a second heater.

Bogen, however, teaches that since various staining procedures require heat at different times to enhance the rate of chemical reaction, a means has been developed to heat slides to different temperatures, independently of the temperatures of other slides (column 1, line 60-column 2, line 5). Therefore it would be obvious to use an instrument with multiple heaters in the

method of Kononen et al and Kalra et al, as taught by Bogen et al, in order to enhance the rate of chemical reaction during staining.

12. With respect to claims 15 and 16, Bogen et al teach a carousel adapted to support a plurality of microscope slides bearing biological samples. A plurality of flat heating stations are provided on the platform, each heating station supporting at least one microscope slide and, in a preferred embodiment, each heating surface supporting a single microscope slide. The heating stations are individually controlled to control temperatures to which the slides are heated (column 2, lines 33-44), since various procedures require heat at different times to enhance the rate of chemical reaction (column 1, line 60-column 2, line 5). Therefore, it would be obvious to include multiple heaters mounted on a carousel with means for monitoring and controlling the temperature of the heaters, as taught by Bogen, in the apparatus of Kalra et al and Kononen et al, in order to enhance the rate of the chemical reaction during staining.

Response to Arguments

13. Applicant's arguments with respect to claims 3, 5-8, 11, 12, 14-23 under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. No claims are allowed.

15. The following references are also cited as art of interest: Bacus et al [US 5,428,690] and Tseung et al [US 5,439,649] teach methods and apparatus for automated staining and assay of tissue specimens.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
04/15/04